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## **REPORT**

### **Study Title:**

Oxidation and Reduction of K32

**Concord Biosciences Study Number:** 035901  
**Concord Biosciences Document Number:**035901-1

### **Data Requirement:**

**OPPTS 830.6314, Oxidation/Reduction: Chemical Incompatibility**

### **Author(s):**

Penny Miner

### **Study Completion Date:**

02-Oct-2017

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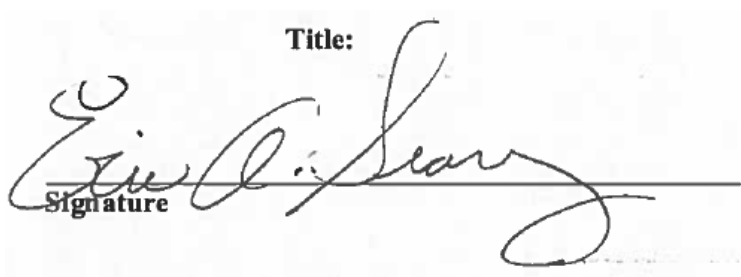

## STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10 (d) (1) (A), (B), or (C).

**Company:**

**Company Agent:**

**Title:**

**Signature**  **Date** 

These data are the property of Koch Agronomic Services, LLC, and, as such, are considered confidential for all purposes other than compliance with FIFRA Section 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other statute or in any other country.

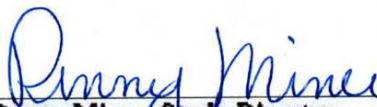


**Report/ Oxidation and Reduction of K32  
Document No. 035901-1**

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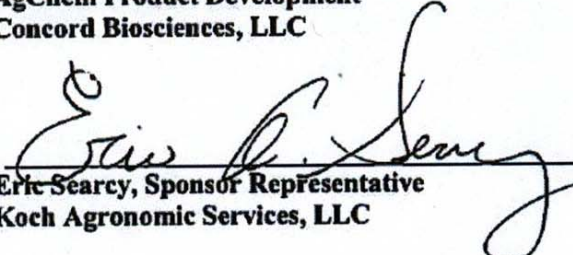
**COMPLIANCE STATEMENT**

The study reported herein, "Oxidation and Reduction of K32" Concord Biosciences, LLC Study Number 035901, was conducted and reported in compliance with the Good Laboratory Practice Regulations set forth in Title 40, Part 160 of the Code of Federal Regulations of the United States of America.

  
\_\_\_\_\_  
**Penny Miner, Study Director**

**AgChem Product Development  
Concord Biosciences, LLC**

October 2, 2017  
\_\_\_\_\_  
**Date**

  
\_\_\_\_\_  
**Eric Searcy, Sponsor Representative**  
**Koch Agronomic Services, LLC**

9/29/2017  
\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Submitter**

\_\_\_\_\_  
**Date**



**Report/ Oxidation and Reduction of K32  
Document No. 035901-1**

## **QUALITY ASSURANCE STATEMENT**

The Concord Biosciences Quality Assurance Unit has performed inspections on the study, "Oxidation and Reduction of K32," Concord Biosciences Study 035901. The results of these inspections, including any findings or observations, were reported to the Study Director and Management for appropriate corrective actions on the dates listed below:

<b>Phase Inspected</b>	<b>Date of Inspection</b>	<b>Dates Reported to the Study Director</b>	<b>Dates Reported to Management</b>
Protocol	March 14, 2017	March 14, 2017	March 14, 2017
In-Study	March 28, 2017	March 28, 2017	March 28, 2017
Protocol Amendment	August 8, 2017	August 8, 2017	August 8, 2017
Data/Report	September 21, 2017	September 22, 2017	September 22, 2017

A handwritten signature in blue ink, appearing to read 'Ann O'Leary'.

**Ann O'Leary, Ph.D.**  
**Concord Biosciences Quality Assurance**

*October 2, 2017*  
**Date**



**Report/ Oxidation and Reduction of K32**  
**Document No. 035901-1**

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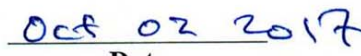
**APPROVALS**

**Study Title:** Oxidation and Reduction of K32  
**Document Number:** 035901-1  
**Testing Facility:** Concord Biosciences, LLC  
AgChem Product Development  
7528 Auburn Road  
Concord, OH 44077

  
\_\_\_\_\_  
**Penny Miner, Study Director**  
**Concord Biosciences, LLC**

  
\_\_\_\_\_  
**Date**

  
\_\_\_\_\_  
**Farhad Sayyapour, Management**  
**Concord Biosciences, LLC**

  
\_\_\_\_\_  
**Date**

## TABLE OF CONTENTS

	<i>Page</i>
TITLE PAGE .....	1
STATEMENT OF NO DATA CONFIDENTIALITY CLAIM .....	2
COMPLIANCE STATEMENT .....	3
QUALITY ASSURANCE STATEMENT .....	4
APPROVALS .....	5
TABLE OF CONTENTS .....	6
LIST OF TABLES .....	6
LIST OF APPENDICES .....	6
CONDUCT OF STUDY .....	7
Sponsor .....	7
Sponsor Representative .....	7
Testing Facility .....	7
Study Director .....	7
Schedule of Events .....	7
Retention of Data .....	8
Sample Receipt and Preparation .....	8
MATERIALS AND METHODS .....	8
Test Substance .....	8
CHEMICAL INCOMPATIBILITY PROCEDURE .....	8
RESULTS .....	9

## LIST OF TABLES

	<i>Page</i>
Table 1: Temperature, °C, Results with K32 for Chemical Incompatibility .....	10
Table 2: Observation Results with K32 for Chemical Incompatibility .....	10

## LIST OF APPENDICES

	<i>Page</i>
APPENDIX A .....	11
Protocol and Amendment .....	11

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## **CONDUCT OF STUDY**

The objective of this study was to determine potential chemical incompatibilities of test materials by understanding the oxidation and reduction properties for K32. This study was conducted under GLP in accordance with the US EPA Product Properties Test Guidelines, OPPTS 830.6314 Oxidation/Reduction: Chemical Incompatibility.

### ***SPONSOR***

Koch Agronomic Services, LLC  
2883 Miller Road  
Decatur GA 30035

### ***SPONSOR REPRESENTATIVE***

Eric Searcy  
Product Regulatory Manager  
Koch Agronomic Services, LLC  
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Phone: 770-593-6813  
Email: eric.searcy@kochind.com

### ***TESTING FACILITY***

Concord Biosciences, LLC  
AgChem Product Development  
10845 Wellness Way  
Concord, OH 44077

### ***STUDY DIRECTOR***

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Concord Biosciences, LLC  
10845 Wellness Way  
Concord, OH 44077  
Phone: (440) 357-3718  
Fax: (440) 357-3654  
Email: penny.miner@concordbio.com

### ***SCHEDULE OF EVENTS***

Study Initiation Date: March 15, 2017  
Experimental Start Date: March 27, 2017  
Experimental Termination Date: May 17, 2017

### ***RETENTION OF DATA***

All original data (including electronic data), or authenticated copies thereof, and a copy of the final report will be retained using appropriate storage media in the archives of Concord Biosciences, LLC upon completion of the study. The Sponsor will be contacted later to determine whether any of the data should be returned, retained or destroyed on their behalf.

### ***SAMPLE RECEIPT AND PREPARATION***

The K32 (lot 55700-30-13) was manufactured at Concord Biosciences on July 20, 2016.

The following are the significant days in this study:

3/27/17 (using deionized water to dissolve K32)

5/16/17 (using dimethyl sulfoxide to dissolve K32)

## **MATERIALS AND METHODS**

The test substance is the test system. The study determined the stability at an elevated temperature for K32.

### ***TEST SUBSTANCE***

Test Substance Name:	K32
Composition:	Reaction products of NBPT with urea and formaldehyde
Batch/Lot Number:	55700-30-13
Analyzed Concentration:	Reaction product mixtures 80.3 wt%, NBPT 17.3 wt%, water 2.4 wt%
Manufactured by:	Concord Biosciences
Date of manufacture:	July 20, 2016
Appearance:	Off-white to pale yellow gel

## **CHEMICAL INCOMPATIBILITY PROCEDURE**

The oxidizing or reducing action was determined in duplicate by adding approximately 5 g of K32 to eight separate 125-mL glass jars with PTFE lined caps. To each of those jars 50 mL of deionized water was added. Due to issues with K32 not being fully soluble in water, the test was repeated using dimethyl sulfoxide (DMSO) as the solvent after method development showed that DMSO was a neutral component and didn't influence the outcome of this test.

A total of eight jars were used for this study. The first two jars served as a control and only contained the test substance and DMSO. In the second set of two jars, approximately 1 g of potassium permanganate was added after the K32 was dissolved in DMSO. The potassium permanganate was added very slowly at a rate that took 1-2 minutes in duration. To the third set of two jars, approximately 1 g of monoammonium phosphate was added after the K32 was dissolved in DMSO. The monoammonium phosphate was added very slowly at a rate that took

1-2 minutes in duration. To the fourth set of jars, approximately 5 g of zinc dust was added after the K32 was dissolved in DMSO. Over approximately 1-2 minutes, the zinc dust was added. All samples were agitated continuously on a wrist action shaker throughout the study.

Observations and temperature measurements were taken immediately after addition of reagent, and then after the 1-hour, 2-hour, 4-hour, and 24-hour intervals. The chemical incompatibility (effervescence, color change, etc.) or temperature rise was recorded.

## **RESULTS**

Observations and temperature measurements were recorded immediately after addition of reagent, after the 1-hour, 2-hour, 4-hour, and 24-hour intervals. Table 1 shows the temperature changes over the 24-hour period. No significant temperature change ( $>5^{\circ}\text{C}$ ) was observed. Table 2 displays the observations that were recorded over the 24-hour period. No changes were observed in the control and the ammonium phosphate after the initial addition. Zinc dust/powder showed a change in color to a cloudy gray. The potassium permanganate only showed a small amount of crystals in the bottom at the 1-hour time point. K32 was considered chemically compatible with potassium permanganate, ammonium phosphate and zinc dust/powder.

**Table 1: Temperature, °C, Results with K32 for Chemical Incompatibility**

Sample	Time					
	Initial	T=0	1 hour	2 hour	4 hour	24 hours
Potassium Permanganate Rep 1	20.9	21.9	22.3	22.3	22.2	23.7
Potassium Permanganate Rep 2	20.8	21.6	22.0	22.3	22.4	24.0
Ammonium Phosphate Rep1	21.1	21.7	22.2	22.8	22.9	23.8
Ammonium Phosphate Rep2	21.0	21.4	22.1	22.1	22.8	24.9
Zinc Dust/Powder Rep 1	21.2	22.0	22.3	22.4	22.4	24.4
Zinc Dust/Powder Rep 2	21.4	22.2	22.3	21.9	22.7	23.8
Control Rep 1	21.6	22.0	22.9	22.3	22.3	24.9
Control Rep 2	21.6	22.0	22.7	22.2	22.2	24.1

T=0 is after addition of reagent

**Table 2: Observation Results with K32 for Chemical Incompatibility**

Sample	Time				
	T=0	1 hour	2 hour	4 hour	24 hours
Potassium Permanganate Rep 1	black granules suspended in the liquid and settling to the bottom	no change	no change	granules settled on the bottom	no change
Potassium Permanganate Rep 2	black granules suspended in the liquid and settling to the bottom	no change	no change	granules settled on the bottom	no change
Ammonium Phosphate Rep1	crystals settling to the bottom	no change	no change	no change	no change
Ammonium Phosphate Rep2	crystals settling to the bottom	no change	no change	no change	no change
Zinc Dust/Powder Rep 1	pasty gray throughout the liquid/clumpy on the bottom	cloudy gray color, settling to the bottom	no change	no change	no change
Zinc Dust/Powder Rep 2	pasty gray throughout the liquid/clumpy on the bottom	cloudy gray color, settling to the bottom	no change	no change	no change
Control Rep 1	thick yellow liquid	no change	no change	no change	no change
Control Rep 2	thick yellow liquid	no change	no change	no change	no change

T=0 is after addition of reagent

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## **APPENDIX A**

### **Protocol and Amendment**

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## **PROTOCOL**

### **Study Title:**

Oxidation and Reduction of K32

**Ricerca Study Number:** 035901

**Ricerca Document Number:** 035901-0

### **Data Requirement:**

OPPTS 830.6314, Oxidation/Reduction: Chemical Incompatibility

#### **Testing Facility:**

AgChem Product Development  
Ricerca Biosciences, LLC  
7528 Auburn Road  
Concord OH 44077

#### **Study Sponsor:**

Koch Agronomic Services, LLC  
2883 Miller Road  
Decatur GA 30035



## TABLE OF CONTENTS

	<i>Page</i>
TITLE PAGE .....	1
TABLE OF CONTENTS .....	2
STUDY INFORMATION .....	3
Study Title .....	3
Ricerca Study Number .....	3
Sponsor .....	3
Sponsor Representative .....	3
Testing Facility .....	3
Study Director .....	3
Purpose and Objectives .....	3
Regulatory Compliance .....	3
Schedule of Events .....	4
TEST SUBSTANCE .....	4
Test Substance .....	4
Storage and Distribution .....	4
Characterization of the Test Substance .....	4
ANALYTICAL PROCEDURES .....	4
Control of Experimental Bias .....	5
Experimental Design .....	5
RECORDS TO BE MAINTAINED .....	5
GLP Compliance .....	5
REPORT .....	6
Amendments and Deviations to the Protocol .....	6
PROTOCOL ACCEPTANCE .....	7



## STUDY INFORMATION

### ***STUDY TITLE***

Oxidation and Reduction of K32

### ***RICERCA STUDY NUMBER***

035901

### ***SPONSOR***

Koch Agronomic Services, LLC  
2883 Miller Road  
Decatur GA 30035

### ***SPONSOR REPRESENTATIVE***

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Product Regulatory Manager  
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Phone: 770-593-6813  
e-mail: eric.searcy@kochind.com

### ***TESTING FACILITY***

Ricerca Biosciences, LLC  
7528 Auburn Road  
Concord, OH 44077

### ***STUDY DIRECTOR***

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Ricerca Biosciences, LLC  
7528 Auburn Road  
Concord, OH 44077  
Phone: (440) 357-3718  
Fax: (440) 357-3654  
Email: penny.miner@ricerca.com

### ***PURPOSE AND OBJECTIVES***

The objective of this study is to determine potential chemical incompatibilities of test materials by understanding the oxidation and reduction properties for K32.

### ***REGULATORY COMPLIANCE***

This study will be conducted in accordance with the US EPA Product Properties Test Guidelines, OPPTS 830.6314 Oxidation/Reduction: Chemical Incompatibility.



### ***SCHEDULE OF EVENTS***

Proposed Experimental Starting Date: March 2017  
Proposed Experimental Termination Date: March 2017

## **TEST SUBSTANCE**

### ***TEST SUBSTANCE***

- **K32**

Composition:	Reaction products of NBPT with urea and formaldehyde
Batch/Lot Number:	55700-30-13
Analyzed Concentration:	Reaction product mixtures 80.3 wt%, NBPT 17.3 wt%, water 2.4 wt%
Manufactured by:	Ricerca Biosciences
Date of manufacture:	July 20, 2016
Appearance:	Off-white to pale yellow gel
Storage:	Refrigerated

### ***STORAGE AND DISTRIBUTION***

Ricerca will supply the test substance which will be stored at refrigerated conditions. All preparations will be made in a manner to preclude contamination or deterioration of the test substance. All preparations of the test substance will be uniquely identified.

Upon completion of the study any portion of the test substance not utilized in the study will remain in storage at Ricerca Biosciences unless otherwise directed by the Sponsor.

### ***CHARACTERIZATION OF THE TEST SUBSTANCE***

It is the responsibility of the Sponsor to provide characterization of the test substance used in this study. The Sponsor will assume the responsibility of retention of a sample of the test substance as specified in 40 CFR 160.195.

## **ANALYTICAL PROCEDURES**

The oxidizing or reducing action will be determined in duplicate by adding approximately 50 g of test substance to eight separate glass jars with PTFE lined caps of appropriate size (typically 125 mL). To each jar, 50-mL deionized water will be added by an appropriate means.

1. The first two jars will serve as a control and will contain only the test substance and deionized water.
2. In the second two jars, approximately 1 g of potassium permanganate will be added by an appropriate means. The potassium permanganate will be added very slowly; typically 1-2 minute duration. The potassium permanganate may be pre-diluted with the 50-mL deionized water and then the entire volume added to the test substance over 1-2 minute duration.
3. To the third two jars, approximately 1 g of monoammonium phosphate will be added by an appropriate means. The monoammonium phosphate will be added very slowly; typically 1-2



minute duration. The monoammonium phosphate may be pre-diluted with the 50-mL deionized water and then the entire volume added to the test substance over 1-2 minute duration.

4. To the fourth set of jars, approximately 5 g of zinc dust will be added by appropriate means. The zinc dust should be added slowly over 1-2 minute duration.
5. Using Teflon coated stir bars, the samples will be agitated continuously throughout the study.

Observations and temperature measurements will occur immediately after addition of reagent, after 1 hour, after 2 hours, after 4 hours and after 24 hour intervals. Any chemical incompatibility (effervescence, color change, etc.) or temperature rise will be recorded. A temperature change of  $>5^{\circ}\text{C}$  will be considered significant.

#### ***CONTROL OF EXPERIMENTAL BIAS***

##### **Experimental Design**

Experimental bias is reduced through analysis of multiple samples and replicate analysis.

#### **RECORDS TO BE MAINTAINED**

Analysts shall document all experimentation such that an experienced scientist can reconstruct the work. Documentation shall include sample identifications, weighings, dilutions, calculations, etc. Additional documentation shall include instrumentation and equipment utilized during the study, as well as documentation of prepared reagents and solutions.

All study data shall be reviewed or verified and maintained in folders in the study activity file. Other comments, descriptions, calculations, correspondence, etc., shall be placed in the study activity file.

Upon conclusion of the study, copies of representative raw data (as appropriate), shall be submitted to the Sponsor. An accurate study file, including original raw data, shall be submitted to the Ricerca Biosciences, LLC Archives, 7528 Auburn Road, Concord, Ohio.

#### ***GLP COMPLIANCE***

The described study will be conducted in accordance with the U.S. Environmental Protection Agency's "Good Laboratory Practice Standards" as published in 40 CFR Part 160. This study will be routinely examined by Ricerca Biosciences Quality Assurance Unit personnel for compliance of GLP, protocol, and SOPs.



## REPORT

A final report will be prepared at the conclusion of the study. The report shall include, but not necessarily be limited to, the following:

- Name and address of the facility performing the study and the dates on which the study was initiated and completed, terminated, or discontinued
- The approved protocol and any amendments to the original protocol
- Reference(s) to, and/or a detailed description of, all methods used
- Representative data generated while conducting the study, and representative transformations, calculations or operations performed on the data
- Identification of the test substances used in the study
- All deviations and changes from the protocol
- A description of all circumstances that may have affected the quality or integrity of the data
- Name and signature of the Study Director, the names of other scientists or professionals, and the names of supervisory personnel involved in the study
- Statistical methods employed for analyzing the data. A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis
- Locations where raw data and the final report are to be stored
- The signed and dated statement by the Ricerca Quality Assurance Unit specifying the dates of study inspections and dates the findings were reported to the Study Director and Management, when applicable
- The signed and dated statement by the Study Director describing compliance with the Good Laboratory Practice Standards as specified in 40 CFR 160

### *AMENDMENTS AND DEVIATIONS TO THE PROTOCOL*

All agreed upon amendments will be expressed in writing, and signed and dated by the Sponsor and the Study Director. Copies of the signed amendments will be returned to the Study Director and appended to the protocol.


The Study Director will communicate the nature of any deviations to the Sponsor. Deviations from the protocol, if any, will be documented and described in the final report.




Protocol/ Oxidation and Reduction of K32  
Document Number: 035901-0

## PROTOCOL ACCEPTANCE

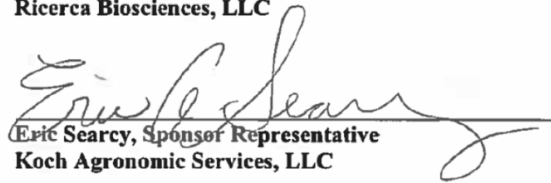
**Study Title:** Oxidation and Reduction of K32  
**Document Number:** 035901-0  
**Testing Facility:** Ricerca Biosciences, LLC  
7528 Auburn Road  
Concord, OH 44077

  
Penny Miner, Study Director  
Ricerca Biosciences, LLC

March 15, 2017  
Date

  
Connie Collins, Management  
Ricerca Biosciences, LLC

15-Mar-2017  
Date

  
Eric Searcy, Sponsor Representative  
Koch Agronomic Services, LLC

3/15/2017  
Date

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## PROTOCOL AMENDMENT ONE

### Study Title:

Oxidation and Reduction of K32

**Concord Biosciences Study Number:** 035901  
**Concord Biosciences Document Number:** 035901-0-1

**Testing Facility:**  
AgChem Product Development  
Concord Biosciences, LLC  
10845 Wellness Way  
Concord, Ohio 44077, USA

**Study Sponsor:**  
Koch Agronomic Services, LLC  
2883 Miller Road  
Decatur GA 30035

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Protocol Amendment One / Oxidation and Reduction of K32  
Document Number: 035901-0-1

---

## ORIGINAL PROTOCOL SECTION

ALL PAGES WHERE THE NAME AND/OR ADDRESS APPEARS:

Ricerca Biosciences, LLC  
AgChem Product Development  
7528 Auburn Road  
Concord OH 44077

## CHANGE TO

Concord Biosciences, LLC  
AgChem Product Development  
10845 Wellness Way  
Concord, OH 44077

## REASON FOR CHANGE

The name and address of the testing facility have changed.

## EFFECTIVE DATE

The effective date is the date that the amendment is signed by the Study Director.

## ORIGINAL PROTOCOL SECTION

ALL INCIDENCES WHERE RICERCA.COM APPEARS IN AN EMAIL ADDRESS OF AN EMPLOYEE  
NOW WITH CONCORD BIOSCIENCES, LLC:

penny.miner@ricerca.com

## CHANGE TO

penny.miner@concordbio.com

## REASON FOR CHANGE

The email addresses of the testing facility have changed.

## EFFECTIVE DATE

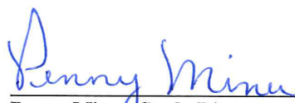
The effective date is the date that the amendment is signed by the Study Director.



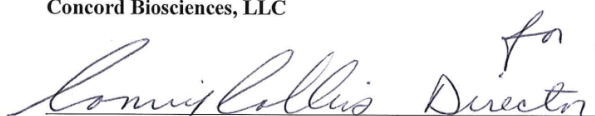
Protocol Amendment One / Oxidation and Reduction of K32  
Document Number: 035901-0-1


## PROTOCOL AMENDMENT ONE ACCEPTANCE

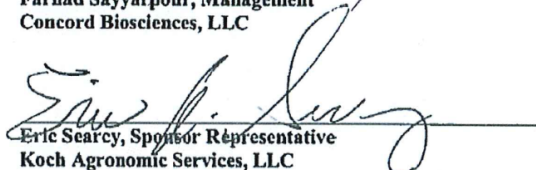
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**Document Number:** 035901-0-1  
**Testing Facility:** AgChem Product Development  
Concord Biosciences, LLC  
10845 Wellness Way  
Concord, OH 44077

  
Penny Miner, Study Director  
Concord Biosciences, LLC

  
September 29, 2017  
Date

  
Farhad Sayyarpour, Management  
Concord Biosciences, LLC

  
29-Sept-2017  
Date

  
Eric Searcy, Sponsor Representative  
Koch Agronomic Services, LLC

  
9/28/2017  
Date